

Application No. 10/790,640  
Amendment dated May 18, 2009  
In response to Examiner's Advisory Action dated March 6, 2009

Docket No.: 103080-P04-026

### **REMARKS**

#### **Claim Status**

Applicants note that the claim amendments in Applicants Response of February 17, 2009 were not entered. Applicants request entry of the amendment submitted with their February 17, 2009 response. The claim amendments from our previous non-entered reply are also listed in the claim listing submitted herewith. Upon entry of the amendments, claims 1, 3-8, 10-12, 14-16, 21-25, 27-36, and 106 constitute the pending claims in the present application.

Applicants have cancelled claims 40-67, which were previously withdrawn. Applicants have also cancelled claims 13, 17-20, 26, 37-39, and 68-105 without prejudice. Applicants reserve the right to pursue the subject matter of the cancelled claims and to pursue claims of similar or differing scope in future applications.

In response to the Advisory Action dated March 6, 2009, Applicants have further amended claims 7, 14, 25, 28, and 106 to more clearly define Applicants' claimed invention. Specifically, Applicants have further amended claim 7 to recite that the mammalian primary cell is transfected with at least one heterologous gene or at least one native gene of the mammalian primary cell is disrupted prior to step (a) of claim 1. Support for this amendment may be found, for instance, in claims 17 and 18 as originally filed. Applicants have further amended claim 14 to recite that the genome of the first mammalian cell has been transfected with at least one heterologous gene or has had at least one native gene disrupted prior to step (a) of claim 8. Support for this amendment may be found, for instance, in claims 19 and 20 as originally filed. Applicants have further amended claim 25 to recite "performing nuclear transfer." Support for this amendment may be found, for instance, paragraph 88 of the published application (2004-0180430). Finally, Applicants have amended claim 28 to correct an inadvertent error, and claim 106 to correct a typographical error.

No new matter has been added. Applicants respectfully request reconsideration of the rejections in view of the following remarks. Applicants now address the Examiner's Advisory Action dated March 6, 2009 and the Final Office Action dated November 17, 2008 below.

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Related Application

Applicants take this opportunity to inform the Examiner of a co-pending, commonly assigned application serial number 11/079,930. Applicants assume the Examiner is aware of this application because it was cited in the recent Office Action. Nevertheless, Applicants also wish to draw the Examiner's attention to the ongoing prosecution in this co-pending application. Applicants will be happy to provide copies of these applications or any papers associated with the prosecution of these applications upon request.

Obviousness-type Double Patenting Rejection

Claim 1 was rejected on the basis of alleged obviousness-type double patenting over claims 1 and 4-6 of US Patent 6,808,704. Applicants respectfully traverse the rejection. In the Response filed February 17, 2009, Applicants argued that claim 1 of the instant application is not rendered obvious by claims 1 and 4-6 of US Patent 6,808,704 because, at least, claim 1 of the instant application recites "said mammalian primary cell is a senescent cell or a cell that is near senescence". Claims 1 and 4-6 of US Patent 6,808,704 contain no such limitation. In the Advisory Action dated March 6, 2009, the Examiner stated that this argument was not persuasive because "this provisional rejection is not a statutory rejection, but is an obviousness type rejection". The Examiner also states, "Furthermore, additional steps recited in the patent fail to render non-obvious the claimed method steps." However, these arguments do not address the question at hand. Given that claims 1 and 4-6 of US Patent 6,808,704 do not recite "senescent cell or a cell that is near senescence", the Examiner has not stated why the concept of "senescent cell or a cell that is near senescence" is suggested by claims 1 and 4-6 of US Patent 6,808,704. To make a *prima facie* case of obviousness-type double patenting, the Examiner must show why the claims of US Patent 6,808,704 teach or suggest all the limitations of claim 1. Applicants respectfully submit that a *prima facie* case of obviousness has not been made. Accordingly, claim 1 of the instant application is not rendered obvious by claims 1 and 4-6 of US Patent 6,808,704.

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In addition, claims 1, 3-8, 10-24, and 29-36 are provisionally rejected on the basis of alleged obviousness-type double patenting over claims 87-92 and 94-117 of copending Application No. 11/079,930. Applicants request that the Examiner hold this provisional rejection in abeyance until otherwise allowable subject matter is identified in the instant application. Once allowable subject matter has been identified, Applicants will evaluate the filing of a terminal disclaimer or providing arguments in view of the claims pending at that time.

Claim rejections under 35 U.S.C. §112, second paragraph

Claims 1, 3-8, 10-28, 30-33, 69-71, 82-84, and 94-96 are rejected under 35 USC § 112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants respectfully traverse the rejection to the extent it is maintained in view of the current amendments.

First, the Office Action rejects claims 1, 21, and 22 for use of the phrase "rejuvenating a primary cell." The Examiner states, "the method as claimed does not result in modifying the cell per se," but "rather results in a different and unique cell," (page 4). In the response dated February 17, 2009, Applicants amended claim 1 to refer to two cells, "a mammalian primary cell" and "a cell of the same type as the mammalian primary cell" and have amended the preamble to read "A method of isolating a cell of the same type as a mammalian primary cell..." Support for this amendment may be found, for example, in part (f) of claim 1 as filed. Similarly, claims 21 and 22 were amended in the response dated February 17, 2009 to remove the term "rejuvenating". In addition, claims 69 and 92, which recited the word "rejuvenated", have been canceled. Accordingly, Applicants believe that claims 1, 21, and 22, and the claims depending therefrom (3-7, 23, and 24) are definite.

Next, the Examiner states, "Claims 7, 14, 82, and 95 remain vague and unclear because the nature of the alteration of the genome is not adequately described," (page 5). Applicants respectfully traverse. Nevertheless, in the response dated February 17, 2009, Applicants amended

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claims 7 and 14, to remove the term "alteration to its genome" and to recite "has been transfected with at least one heterologous gene or has had at least one native gene disrupted." Support for the amendment may be found, for example, in originally-filed claim 17 which reads "...wherein said genetic alteration comprises the transfection of at least one heterologous gene," and originally-filed claim 18 which reads "...wherein said genetic alteration comprises the disruption of at least one native gene." Applicants also amended claims 7 and 14 to specify that the recited genetic alterations are induced to the mammalian primary cell prior to step (a) of claims 1 and 8, respectively. Claims 82 and 95 have been canceled. Accordingly, Applicants believe that claims 7 and 14 are definite.

The Examiner also states, "Claim 13 remains unclear in the recitation of 'for transplantation into a patient in need of a transplant' because it is unclear if this is an intended use for the tissue or a limitation wherein the tissue generated must be capable of being transplanted," (page 6). Applicants respectfully disagree. Nevertheless, solely to expedite prosecution, Applicants have cancelled claim 13, thereby obviating the rejection.

Next, the Examiner states that "Claim 25 remains confusing and unclear because an animal with the same genotype cannot be genetically different so cannot be altered... It is not clear what standard the term 'altered' is in comparison to," (page 6). In the response dated February 17, 2009, Applicants rewrote claim 25 to incorporate verbatim much of the text of claim 21 rather than referring to it. In addition, Applicants removed the phrase "having the same genotype as the cell of Claim 24" from the preamble. In the recent Advisory Action, the Examiner objected to the term "using" in line 4 of claim 25. Applicants have herewith amended this portion of claim 25 to recite "performing nuclear transfer by transferring the nucleus..." rather than "using nuclear transfer..." Accordingly, Applicants believe that claim 25 is definite. Claim 26, which depended from claim 25, has been cancelled. In addition, Applicants amended claim 24 (which refers to claim 21) to remove the term "genetically altered."

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Finally, the Examiner states that "Claim 84 remains unclear because the metes and bound of the terminology 'substantially the same' is unclear." Applicants respectfully disagree, but nevertheless have cancelled claim 84.

In light of the claim amendments and remarks above, reconsideration and withdrawal of the indefiniteness rejection is respectfully requested.

Claim rejections under 35 U.S.C. §102(a) and (e)

Claims 21, 25-28, 37-39, 69-78, 80-92 and 94-105 are rejected under 35 U.S.C. §102(a) and (e) as allegedly being anticipated by Strelchenko *et al.* (US Patent 6,011,197) or Damiani *et al.* (US Patent 6,258,998). Applicants respectfully traverse the rejection.

First, the Examiner states that "claims 21, 69-78, 80-92, and 94-105 are **product by process** claims" (page 7, emphasis added) and states that "[s]uch cloning products do not differ from any other standard cloning protocols that may differ in method steps from the claimed processes," (page 7). Contrary to the Examiner's assertion, Applicants point out that claim 21 is a method claim, reciting "A method of performing compound genetic manipulations in a mammalian primary cell, comprising..." Furthermore, claim 21 contains a limitation of "wherein said mammalian primary cell is passaged to a senescent or near-senescent state prior to nuclear transfer." Applicants submit that the use of senescent or near-senescent cells for nuclear transfer is neither expressly nor inherently disclosed in Strelchenko *et al.* or Damiani *et al.* Accordingly, Applicants believe claim 21 is novel.

Regarding claims 69-78, 80-92, and 94-105, Applicants believe these compositions of matter (e.g. cells) have material differences from cells described in the cited publications. Nevertheless, solely to expedite prosecution, Applicants have canceled claims 69-78, 80-92, and 94-105 and intend to pursue this subject matter in a continuing application.

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Next, the Examiner states that "Claims 25-26 are drawn to recloning methods to result in a cloned animal wherein the donor cell has been genetically modified," (page 7). Applicants have canceled claim 26, thus rendering the rejection moot as to this claim. Claim 25, as currently amended, recites the phrase "wherein said mammalian primary cell is passaged to a senescent or near-senescent state prior to nuclear transfer". Strelchenko *et al.* and Damiani *et al.* do not teach the use of senescent or near-senescent cells for nuclear transfer donors. Accordingly, Applicants believe that claim 25 is novel.

Furthermore, Applicants submit that claims 27 and 28 are drawn to methods of recloning non-human mammalian animals using donor cells that are senescent or near senescence. Applicants submit that neither Strelchenko *et al.* nor Damiani *et al.* teaches using these types of cells. Accordingly, Applicants believe claims 27 and 28 are novel.

The Examiner also states, "Claim 37 merely requires transfer of a nucleus into a recipient oocyte," (page 7). Applicants respectfully disagree. Nevertheless, Applicants have canceled claim 37 and its dependent claims (38 and 39).

Accordingly, Applicants submit that claims 21, 25, 27, and 28 are not anticipated by Strelchenko *et al.* and Damiani *et al.* Reconsideration and withdrawal of this rejection is respectfully requested.

Claim rejections under 35 U.S.C. §102(b)

According to the March 6, 2009 Advisory Action, the rejection of claims 21, 25-28, 37-39, 69-78, 80-92, and 94-105 as being allegedly anticipated by Robl *et al.* (WO98/07841) as evidenced by Evans *et al.* (Nature Genetics 23:90-93, 1999) has been withdrawn. Applicants acknowledge with appreciation the Examiner's withdrawal of the rejection under 35 U.S.C. § 102(b).

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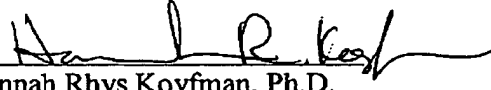
### CONCLUSION

In view of the above amendments and remarks, Applicants believe the pending application is in condition for allowance.

Applicants believe no fee is due with this response other than those listed on the accompanying transmittal. However, if any additional fee is due, please charge our Deposit Account No. 18-1945, under Order No. 103080-P04-026 from which the undersigned is authorized to draw.

Dated: May 18, 2009

Respectfully submitted,

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